

**Remarks/Arguments:**

**Introduction**

Claims 1-9, 11-24, 27-37 and 41 are pending. Claims 39 and 40 are canceled without prejudice to the filing of a divisional or continuation application. Claims 1 and 23 have been non-narrowingly amended to describe that the length of the stent includes a length of a curved segment therein and have also been amended to describe that all the stent wires and their turns are distributed substantially equally along the length of the prosthesis. Claim 41 has been added. Support for claim 41 may be found in claim 1 and in the specification at page 10 in the paragraph beginning with "The stent may...".

**Section 102 Rejections**

Claims 1, 2, 8, 9, 11-16, 21, 23, 24, 27-32 and 37 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 4,994,071 to MacGregor (hereinafter "MacGregor") as evidenced by U.S. Patent No. 4,733,665 to Palmaz (hereinafter "Palmaz"). Claims 1, 2, 4, 8, 9, 18, 19, 21-24, 34, 35 and 37 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 5,653,743 to Martin (hereinafter "Martin"). Applicant respectfully traverses.

**MacGregor "as evidenced" by Palmaz**

MacGregor describes a bifurcated stent 10 having a main tubular body or lattice 16 and two tubular legs or lattices 20, 23. (MacGregor, column 3, lines 54-68, Fig. 1). The lattices 16, 20, and 22 have a series of loops 12, 12'', 12', respectively, which are depicted as undulating looped wires. (*Id.*) A longitudinally extending wire 24 interconnects loops 12 and 12' and further interconnects lattices 10 and 22. (MacGregor, column 4, lines 1-4). A second longitudinally extending wire 26 similarly interconnects loops 12 and 12'' and lattices 10 and 20. (MacGregor, column 4, lines 5-10).

The stent portion 16, 20 and 22 are depicted in Figs. 1 and 1A as being substantially straight members, i.e. having no segments of curvature along any longitudinal axis. The wires 24, 26 are substantially straight in the longitudinal direction except for a bend at the point of bifurcation. (MacGregor, column 4, lines 10-14; Fig. 1). Thus, as depicted in Fig. 1, the wires 24, 26 do not have turns that are distributed substantially equal along the length of the stent because the wires have only one bend at the point of bifurcation which is the point of curvature being cited by the Examiner. Further, MacGregor fails to describe that any of the loops 12, 12', 12'' extend through the area of bifurcation. In other words, there is a discontinuity of the stent configuration at the area of bifurcation. (see e.g., MacGregor, Fig. 1A). The general depictions of Figs. 2A-3D, which schematically show the placement of the MacGregor stent within body vessels 50, 50a, 50b, depict portions of the stent being curved, but fail further detail the area of bifurcation, i.e., fails to show any wires and their turns being distributed substantially equally along the length of the device, including being distributed substantially equally along the portion of curvature..

In contrast, the present invention as currently defined by independent claims 1, 23 and 41 is directed to a prosthesis comprising, *inter alia*, a stent scaffold consisting essentially of or comprising wires having turns wherein the wires and their turns are distributed substantially equal along the length of the prosthesis which includes, *inter alia*, at least one segment of curvature. MacGregor fails to disclose such claimed limitations because the wires 24, 26 only have one turn at the point of bifurcation and the turn is not therefore equally distributed along the length of the stent. Further, the stent coils 12, 12', 12'' are not equally distributed over the length of the stent due to discontinuity at the point of bifurcation.

The Examiner acknowledges these deficiencies in MacGregor because the Examiner attempts to use a secondary reference in the section 102(b) rejection, as follows:

**Regarding the limitation "wherein the wire and its turns are distributed substantially equally along the length of the prosthesis.", MacGregor discloses that other stent patterns**

**may be used to make the bifurcated stent (Column 4 lines 19-35), particularly Palmaz '665. The stent pattern disclosed in this patent shows that the turns of the wire are distributed substantially equally along the length of the stent FIG. 1A). (Office Action dated October 19, 2004, page, 2)**

Firstly, MacGregor fails to incorporate the contents of Palmaz by reference. Thus, the Action's reliance on Palmaz to correct the deficiencies of MacGregor is not appropriate. Nevertheless, that Examiner states that the combination is proper under MPEP §2131.01. Under MPEP §2131.01, a rejection over multiple references under Section 102(b) may be proper when the extra reference is cited to:

- (A) Prove the primary reference contains an "enabled disclosure;"**
- (B) Explain the meaning of a term used in the primary reference; or**
- (C) Show that a characteristic not disclosed in the reference is inherent.**

Thus, the "undisclosed feature" of MacGregor must be inherent. As the Action failed to provide any arguments relating to inherency, reliance on the secondary reference in the Section 102(b) rejection is improper, and the rejection should be withdrawn.

Accordingly, MacGregor fails to disclose the present invention. Reconsideration and withdrawal of the Section 102(b) rejections over MacGregor are respectfully requested.

Further, even if the references were combined, MacGregor and Palmaz, individually or in combination, fail to disclose, teach or suggest the present invention. As specifically shown in Fig. 1A of Palmaz, the stent of Palmaz is a substantially straight stent. Palmaz, including Fig. 1A of Palmaz which is specifically cited by the Examiner, fails to disclose, teach or suggest its stent may be curved. More particularly, Palmaz fails to disclose, teach or suggest a curved stent having its stent wires distributed substantially equally along its length, including a curved stent segment. Further, MacGregor fails to disclose, teach or suggest that either its coils or wires and their configurations, i.e., turns, may be equally distributed over the entire length of

the stent, especially and including the curved portions such as the bifurcation location. Thus, Palmaz fails to cure the deficiencies of MacGregor.

The only teaching on the record of a curved stent having its stent wires distributed substantially equally along its length, including a curved stent segment, is the subject application. Any attempt at hindsight reconstruction to arrive at the claim limitations of the subject invention is strictly prohibited. *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1445-46 (Fed. Cir. 1993).

Moreover, the cited references must be considered for the entirety of their teachings. *Bausch & Lomb, Inc. v. Barnes-Hind, Inc.*, 230 U.S.P.Q. 416, 419 (Fed. Cir. 1986). It is impermissible during examination to pick and choose from a reference only so much that supports the alleged rejection. *Id.* Thus, the specific disclosure and teachings of MacGregor that teach away from the present invention must be considered by the Examiner. For example, the stent of MacGregor requires the presence of wires 24, 26. As these wires are obliquely bent only at the point of bifurcation, such a single deflection point cannot be construed as being a stent wire having substantially equal turns along the length of the stent. Further, if the stent wires 24, 26 were somehow removed from the device of MacGregor, the resulting stent would be inoperable as there would be no linking members among the individual undulating wires 12 to hold the device together. An inoperable reference cannot form a basis for a *prima facie* case of a rejection. *In re Gordon et al.*, 221 U.S.P.Q. 1125, 1127 (CAFC 1984). Further, in the case of attempting to combine references, such an inoperable reference is a teaching away of the present invention. *Id.*

Thus, MacGregor and Palmaz, individually or in combination, fail to disclose, teach or suggest the subject invention as presently defined by independent claims 1, 23 and 41. Therefore, reconsideration and withdrawal of the claim rejections are respectfully requested.

Martin

Martin is directed to a prosthesis 1 having a graft 2 having a woven, stainless steel, self-expanding mesh support 3 bonded to the graft 2. (Martin, column 2, lines 49-57) (emphasis added). The prosthesis 1 is shown as being curved in both Figs. 1 and 4. Fig. 1 depicts details of the prosthesis 1, and Fig. 4 schematically depicts placement of the prosthesis in a hypogastric artery. (Martin, column 2, lines 34-43). In Fig. 1, Martin shows prosthesis 1 as having a large end 6 tapering down to a smaller end 6. Martin shows wire crossings at the large end 5, but fails to show any wire crossing details at the smaller end 6 or portions therebetween. While the Applicant has argued that the wire crossing at end 5 has a gradient of wire crossings, i.e., increased separation of the wires at the top of the illustrated portion as compared to the decreased separation at the bottom of the illustrated portion, the Examiner rejected such an argument. The applicant would like to point out that if the Examiner observes the crossings at the middle of the device, there is apparently less distance between the crossing wires towards the bottom of the illustrated portion. Applicant respectfully requests the Examiner to reconsider her visual examination of the figure.

Even if the Examiner maintains her position regarding the crossing density at the illustrated portion in Fig. 1, Martin clearly fails to show or describe the crossing density of the wires at the smaller end 6 and at the tapered portions therebetween. Moreover, the cited Martin reference must be considered for the entirety of its teachings. *Bausch & Lomb, Inc. v. Barnes-Hind, Inc.*, 230 U.S.P.Q. 416, 419 (Fed. Cir. 1986). It is impermissible during examination to pick and choose from a reference only so much that supports the alleged rejection. *Id.* Thus, the Examiner may not ignore the deficiencies of Martin which include, *inter alia*, not crossing details towards the tapered end 6 of the device.

The only teaching of record of a prosthesis comprising, *inter alia*, a stent scaffold consisting essentially of or comprising wires having turns wherein the wires and their turns are distributed substantially equal along the length of the prosthesis which includes, *inter alia*, at

least one segment of curvature is the Applicant's own disclosure. Thus, the Examiner's attempt to describe the crossing density of Martin as being constant over the entire length of the prosthesis must involve hindsight reconstruction as Martin is silent on that aspect. Any attempt at hindsight reconstruction to arrive at the claim limitations of the subject invention is strictly prohibited. *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1445-46 (Fed. Cir. 1993).

Thus, because Martin fails to show the density or frequency of the wire crossings at its tapered portion, especially towards the tapered end 6, Martin fails to disclose each and every element of the present invention as presently recited in independent claims 1, 23 and 41, i.e., Martin fails to disclose stent wires having turns that are distributed substantially equally along the length of the device, including being distributed substantially equally along the region of curvature. Moreover, as Martin is limited in its teachings to a woven product, Applicant respectfully submits that Martin fails to disclose the braided device of claim 41.

Thus, reconsideration and withdrawal of the claims rejections under Section 102(b) over Martin are respectfully requested.

Further, Martin fails to teach or suggest any distribution of a stent wire at its smaller end 6 and at tapered portions between the smaller end 6 and the larger end 5. Thus, Martin fails to teach or suggest an equal distribution of a stent wire and its turns over the length of its graft. Any attempt to modify Martin to include an equal distribution of a wire and its turns must be based on a teaching or suggestion of another reference. As the Examiner is well aware, the subject application cannot be the source of such teaching or suggestion because hindsight reconstruction is strictly prohibited.

Thus, independent claim 1, 23 and 41 are patentably distinct over Martin. Reconsideration and withdrawal of the claim rejections are respectfully requested.

### **Section 103 Rejections**

Claims 3, 5, 6, 7, 17 and 33 are rejected under 35 U.S.C. §103(a) as being obvious over Martin in view of WO 95/09585 (hereinafter "Cato"). Claims 20 and 36 are rejected under 35 U.S.C. §103(a) as being obvious over Martin in view of U.S. Patent No. 5,695,517 to Marin et al. (hereinafter "Marin"). Applicant respectfully traverses.

Cato discloses a three-dimensionally curved prosthesis. (See e.g., Cato, Fig. 5). The prosthesis includes a tube of bio-compatible material held open by a stent. (Cato, page 6, lines 4-9). Cato, however, fails to teach or suggest any stent details, including details of stent wire distribution and/or configuration. Thus, Cato fails to cure the above-discussed deficiencies of Martin.

Marin describes a graft stent complex 44 L, R which has cephalic stents 48 and caudal stent 49 L, R disposed at opposing ends of knitted textile graft 45 L, R. (Marin, column 6, lines 35-40). In other words, the prosthesis of Marin is a knitted textile graft with stents disposed at the ends of the graft for securement purposes. Further, Marin teaches that the stents, which are secured only to the ends of the grafts, should not extend into the pathological defect, i.e., the curved aneurysm region, and should not extend into branched regions. (Marin, column 20, lines 46-40). Therefore, as noted by the Examiner, the graft 46 L, R has a segment of curvature. Marin, however, fails to teach or suggest a stent having such a curvature. Further, Marin fails to teach or suggest a prosthesis comprising a stent wire having turns that is equally distributed over the length of the prosthesis, including at least one curved segment of the prosthesis.

Moreover, Marin teaches that the stent portions of its prosthesis must not extend along the entire length of the prosthesis. Marin teaches that its stent portions must not traverse curved bodily regions, such as aneurysms, or branched regions. Accordingly, Marin fails to

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teach or suggest the present invention because its stent portions do not extend along the length of its device.

Thus, Martin fails to cure the deficiencies of Martin.

Therefore, reconsideration and withdrawal of the claim rejections are respectfully requested.

#### Summary

Therefore, Applicants respectfully submit that independent claims 1, 23 and 41, and all claims dependent therefrom, are patentably distinct. This application is believed to be in condition for allowance. Favorable action thereon is therefore respectfully solicited.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number given below.

A Petition for an Extension of Time and the corresponding fee is being concurrently filed herein with.

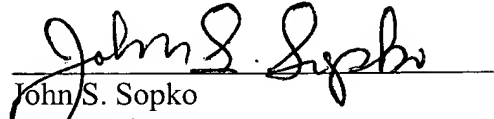
The Commissioner is also hereby authorized to charge payment of any additional fees associated with this communication, or credit any overpayment, to Deposit Account No. 08-2461. Such authorization includes authorization to charge fees for extensions of time, if any, under 37 C.F.R. § 1.17 and also should be treated as a constructive petition for an extension of time in this reply or any future reply pursuant to 37 C.F.R. § 1.136.



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Further, please kindly send all further correspondence relating to the subject application to the attorney of record at the address indicated below.

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